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antigen and a mucosal binding component selected from the group consisting of a cholera toxin B peptide (CTB) or an *E. coli* heat-labile enterotoxin B subunit (LTB) peptide in an unconjugated form.

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### REMARKS

Claims 1-26 are pending in this application, with claims 21-26 withdrawn from consideration as drawn to a non-elected invention. By this Amendment, claim 4 has been canceled and claims 1, 6, 12, 19 and 20 have been amended, leaving claims 1-3 and 5-20 under consideration. The specification has been amended to correct two obvious typographical errors. Support for the amendments to claims 1, 6, 12, 19, and 20 may be found, for example, at page 6, line 25, page 13, lines 8-12, and page 17, lines 8-9. No new matter has been added.

#### Rejections under 35 USC § 112, first paragraph

Claims 1, 2, and 4-20 stand rejected under 35 USC § 112, first paragraph, as allegedly not enabled. The Examiner asserts that the specification is not enabling for all mucosal binding components, but rather only for the mucosal binding component cholera toxin B (CTB).

Applicant respectfully traverses this ground for rejection.

Applicant respectfully submits that the specification is fully enabling for mucosal binding partners (MBPs). The properties of MBPs are discussed in the specification (see pages 15-18), including a list of MBPs useful in the invention (see page 15). Additionally disclosed are methods of identifying MBPs (see page 16). However, in the interests of expediting prosecution, Applicant has amended the claims to recite the MBPs CTB and LTB. The Examiner has admitted that the use of CTB is enabled by the specification, and Applicant respectfully submits that LTB is also enabled. LTB and methods of obtaining it are described at pages 17 and 18 of the application. In view of the detailed disclosure of the mucosal binding partner LTB and the Examiner's admission that CTB is enabled, Applicant respectfully submits that the instant claims



are fully enabled by the specification. Accordingly, Applicant respectfully submits that this ground for rejection has been obviated and respectfully requests that it be withdrawn.

Rejections under 35 USC § 112, second paragraph

A. Claim 4 stands rejected under 35 USC § 112, second paragraph, as allegedly indefinite. The Examiner asserts that the term “unassociated” is unclear. Applicant respectfully traverses this ground for rejection.

Applicant has canceled claim 4 without prejudice or disclaimer. Accordingly, this ground for rejection has been rendered moot and Applicant respectfully requests that it be withdrawn.

B. Claim 6 stands rejected under 35 USC § 112, second paragraph, as allegedly indefinite. The Examiner asserts that the term “bystander” is unclear. Applicant respectfully traverses this ground for rejection.

Applicant has amended claim 6 to recite the term “bystander **antigen**” (emphasis added). The term “bystander antigen” is fully defined in the specification, in the “Definitions and general techniques” section of the application (see page 13, lines 8-12). Accordingly, Applicant respectfully submits that this ground for rejection has been rendered moot and respectfully request that it be withdrawn.

Rejections under 35 USC § 103(a)

Claims 1-20 stand rejected under 35 USC § 103(a), as allegedly obvious over Japanese patent abstract no. JP3109328 (“JP abstract”) in view of Elson (1989, *Curr. Top. Microbiol.* **146**:29-33). The Examiner asserts that the JP abstract teaches that the administration of CTB prevents bone marrow transplantation, and that Elson teaches that intestinal administration of admixtures of CTB plus antigen do not stimulate an antibody response. Applicant respectfully traverses this ground for rejection.



Applicant respectfully submits that the JP abstract and Elson, alone or in combination fail to teach or suggest the instant claimed methods of tolerization. The JP abstract teaches only that administration of CTB reduces transplant rejection and that CTB should be administered prior to transplantation. Nothing in the JP abstract teaches or suggests any immune tolerization activity of CTB, nor does it teach or suggest mucosal administration of CTB. The Elson reference fails to cure the deficiencies of the JP abstract. Elson describes experiments which investigate the adjuvant properties of CTB, a highly immunogenic protein. At the paragraph bridging pages 30 and 31, Elson teaches that a mixture of CTB and keyhole limpet hemocyanin (KLH), administered to the intestine, failed to elicit an antibody response. However, a failure to elicit an immune response neither teaches nor suggests anything about tolerization. Accordingly, in view of the failure of either cited reference to teach immune tolerization by CTB when administered to the mucosa, the cited references cannot teach the instant invention. In view of the failure of the cited references to teach the claimed invention, Applicant respectfully submits that this ground for rejection is without merit and respectfully requests that it be withdrawn.

In view of the amendments and arguments presented herein, Applicant believes the claims are in condition for allowance. Early notification to this effect is earnestly solicited. In the event that Examiner Swartz finds any issues remain, he is respectfully requested to contact the undersigned agent at 650-813-5816.




In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 273802002200. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

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